



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/631,831

08/01/2003

Damien Michel Andre Camelot

087258-0301

1704

22428 7590 08/07/2009
FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

PRATT, HELEN F

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

08/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DAMIEN MICHEL ANDRE CAMELOT
and ELIZE WILLEM BONTENBAL

Appeal 2009-003055
Application 10/631,831
Technology Center 1700

Oral Hearing Held: June 25, 2009

Before JEFFREY T. SMITH, MARK NAGUMO, and
MICHAEL P. COLAIANNI, Administrative Patent Judges

ON BEHALF OF THE APPELLANT:

GILBERTO M. VILLACORTA, ESQUIRE
Foley & Lardner, LLP
3000 K Street, N.W.
Suite 500
Washington, D.C. 20007-5143
(202) 295-4621
(202) 672-5399 – fax

1 The above-entitled matter came on for hearing on Tuesday,
2 April 21, 2009, commencing at 1:49 p.m., at the U.S. Patent and
3 Trademark Office, 600 Dulany Street, Alexandria, Virginia, before
4 Victoria L. Wilson, Notary Public.

5 THE USHER: Calendar number 72. Mr. Talapatra.

6 JUDGE SMITH: Welcome, Mr. Talapatra. Before we begin,
7 could you please introduce your guests.

8 MR. TALAPATRA: Yes. This is Dr. Gilberto Villacorta. He
9 is the partner on the case that I will be advocating.

10 MR. VILLACORTA: I'm also on Brief.

11 JUDGE SMITH: You are also on Brief. Okay. Thank you.

12 JUDGE SMITH: As you know, you have 20 minutes to present
13 your arguments and you can begin when you are ready.

14 MR. TALAPATRA: Good afternoon, your Honors, and thank
15 you for hearing this case this afternoon.

16 I recognize that this case has been briefed so I would like
17 to spend the 20 minutes that I have been granted to highlight those
18 specific issues that Appellant would like to have resolved by the
19 Board today.

20 To do so, I do not believe that I will require all of the time that's
21 been allotted to us but I would like to use any remaining time as an
22 opportunity to address any questions that you may have remaining.

23 Your Honors, the present case is before you today in substantial
24 part to resolve a factual dispute which bears on the sole legal issue at
25 hand.

26 The claims, you may note, are directed to compositions

1 comprising and methods of employing crystalline lactic acid
2 accompanied with a wetting agent, the use of which enables the
3 encapsulation of these crystals. I'll discuss more the role of the
4 wetting agent in addressing the obviousness rejection.

5 Crystals, as your Honors may know, are solid materials
6 whose constituent molecules, here molecules of lactic acid, are
7 arranged in an orderly repeating pattern in all three spatial
8 dimensions and, as such, crystals have some specific advantages
9 over their amorphous counterparts.

10 For example, as we see in the present invention is the
11 ability to incorporate more of the material in a given encapsulated
12 space.

13 Now, crystals, while solid, are not necessarily, quote,
14 anhydrous, nor, quote, "dry," and should not be confused as such.

15 Indeed, many molecules are crystalized with water molecules
16 down to them.

17 JUDGE NAGUMO: What is the difference -- where is the
18 error in the Examiner's rejection as you see it? We are reasonably
19 familiar with the background in the case so what would you point
20 to and say that's error?

21 MR. TALAPATRA: Factually speaking, the Examiner has
22 alleged, at least in three different -- at least in eight different instances,
23 that the lactic acid in the prior art compositions are crystalline. She
24 alleges this because, for example, they are dry or that they are
25 anhydrous. And that's a factual error. Particularly --

26 JUDGE NAGUMO: Is there evidence that the dried lactic acid

1 on the substrate, the calcium lactate or whatever it happens to
2 be, is not crystalline?

3 MR. TALAPATRA: The evidence, your Honor, Appellants
4 would respectfully submit, is in the textbooks and common
5 knowledge to one of ordinary skill in the art. Specifically, because –
6 just because a liquid is absorbed onto a dry carrier does not make
7 that liquid now a solid product.

8 JUDGE NAGUMO: Well, what I am getting at is if I take
9 some salt water and I dry it --

10 MR. TALAPATRA: Correct.

11 JUDGE NAGUMO: -- and I look at what's there after it is
12 dry, I'll see a fair number of small little cubes, cubicle crystals of salt,
13 and all I have done is dry it and it may be somewhat hydrated. Why
14 isn't that the case here?

15 MR. TALAPATRA: For two reasons, Examiner. One is the
16 prior compositions haven't been dried to a sufficient extent to be able
17 to remove water, so there is no evidence, as a matter of fact, there is
18 evidence to the contrary, that the processes that have been used are
19 well below 100 degrees that would be required to dry out the
20 composition.

21 JUDGE NAGUMO: Well, you have told us that the crystals
22 can have water in them, water of hydration in them, so we don't need
23 to get rid of all of the water, what we need is some evidence or
24 reasoned argument that the lactic acid that was dried on the substrates,
25 that I think Percel especially talks about, why isn't that crystalline?

26 That seemed to be -- maybe it isn't the clearest expression I

1 have ever seen but the argument from the Examiner seemed to be,
2 well, they dried it out on this substrate and it is crystalline or at least
3 likely to be crystalline. Why is that error?

4 MR. TALAPATRA: Two points. One is that there is evidence
5 in the record that it is not that trivial to get crystals of lactic acid.

6 JUDGE NAGUMO: Well, what kind of crystals? Schouten
7 was trying to X-ray single quality crystals. Those are hard to get
8 or they can be. And the other one was --

9 MR. TALAPATRA: But Schouten references an article that
10 was published, I believe the first time, of any kind of crystallization.
11 Schouten, you are right, your Honor, gets to a particular level of
12 purity, not just mere crystallization, but even the reference they cite to
13 required two carefully controlled fractional distillations requiring oil
14 pumps to remove all solvents followed by a crystallization step, not by
15 any solution but by ethyl and isopropyl ethers, and even Schouten
16 started with that protocol and then added to that protocol to be able to
17 get crystals.

18 And Appellants would respectfully submit, your Honor, that
19 if mere removal of water would have done the trick, if you will, they
20 would have used a much less laborious approach to get crystals, even
21 if -- even if impure.

22 The second issue that I would like to talk about with respect to
23 the facts is the Examiner also refers to, quote, "anhydrous" crystal and
24 lactic acid, anhydrous lactic acid being present in Percel.

25 This is factually untrue and I would like to point that out, as
26 well.

1 Percel merely calculates the percentage of lactic acid based as a
2 percentage of the total lactic acid carrier composition as if anhydrous.
3 And there are two references that make this clear, I respectfully
4 submit.

5 For example, at column 11, lines 15, Percel, in describing the
6 percentage of lactic acid in the compositions, mentions that, quote,
7 "The product composition data ignored free water content which was
8 included in the percent lactic acid values. Thus, the percent lactic acid,
9 quote, 'as anhydrous, 'would be few percent less than those given."

10 JUDGE NAGUMO: That sort of begs the question in a sense,
11 though, doesn't it, the Examiner is asserting that the lactic acid that's
12 been dried on the substrate that Percel talks about is inherently crystal.

13 MR. TALAPATRA: The issue is that it is not dried -- I mean
14 the product that you see is dried, however, the liquid remains a liquid.
15 It is similar to if I spilled some water on this podium and I use some
16 desiccant to absorb it, if I could, in theory, squeeze that desiccant, I
17 wouldn't get ice to come out, I would have liquid water, and that's
18 what we are seeing here.

19 So the Examiner's assertion is not possible in the sense
20 that not only will you not get crystalline lactic acid, you will
21 not get a solid in those dry particles.

22 The other quote that I would like to bring to your attention,
23 your Honors, is the quote where Percel expressly notes that free water
24 remains in the compositions following spraying of the lactic acid,
25 again going to the point that these compositions are not anhydrous and
26 they retain water within the compounds.

1 That line can be found between lines 11 and 14 at column 3.

2 Aside from the factual issue, I would like to turn your
3 attention, if you will, your Honors, to the Brief, briefly to the sole
4 legal issue.

5 The Examiner alleges that it would have been obvious to
6 encapsulate crystalline lactic acid, being that encapsulated
7 solid acids had been described or encapsulating a liquid lactic
8 acid upon a carrier had been described, as well. That would be
9 the Percel reference.

10 I'll not reiterate all the arguments of record only to mention that
11 the evidence of record is not consistent with the Examiner's
12 proposition. First, the Percel reference that the Examiner relies
13 heavily upon states, quote, "It has thus far been impossible to use
14 crystalline lactic acid for acidulation," and it is for that reason that
15 Percel -- before I get to the reason, Percel further provides a reason for
16 the lack of theretofore success at being able to use crystalline lactic
17 acid for acidulation, which is also noted at the outset in the
18 Applicant's specification, namely, that the crystals of lactic acid are
19 unstable owing to their hygroscopicity.

20 In other words, the crystals liquefy easily which had heretofore
21 prevented their being able to be encapsulated where the prior art had
22 shown encapsulated of other acid solids.

23 And, also, for this reason, Percel foregoes pursuing crystalline
24 lactic acid but opts for spraying liquid lactic acid onto a solid carrier
25 before encapsulating it.

26 The Appellants solved this problem of hygroscopicity by using

1 a wetting agent and prior to the -- prior to which disclosure the
2 ordinary artisan simply had no expectation of success in encapsulating
3 crystalline with lactic acids and absent such expectation, Appellants
4 respectfully submit that a prima facie case for obvious simply cannot
5 be sustained.

6 That's all I had prepared, your Honors. I would like to use any
7 remaining time if you have any outstanding questions.

8 JUDGE SMITH: In your specification, I believe it is page 8,
9 you describe your preferred method for producing your crystalline
10 particles. How does that differ from the process described in Percel
11 in his examples.

12 MR. TALAPATRA: The processes are essentially going to be
13 substantially similar in the sense that they are using fluid bed
14 processors to spray lactic acid onto a carrier.

15 Now, in the present invention, the same process can be used,
16 however, far less of any additive, so to speak, is required.

17 JUDGE SMITH: Furthermore, I believe it is in column -- let's
18 see -- I believe Percel describes that their conditions are down to about
19 less than 13 percent moisture in the process.

20 So with the conditions expressed in table 1 and at less than 13
21 percent moisture content, it is your opinion that you are not going to
22 have any crystals obtained.

23 MR. TALAPATRA: That is our opinion.

24 JUDGE NAGUMO: And the evidence for that would be what?

25 MR. TALAPATRA: The evidence for that would be twofold;
26 one being that even at 13 percent moisture, you are still having liquid

1 that's been absorbed onto a carrier, similar to water onto a sponge,
2 and, second, that crystals -- even if I was to grant that solids were
3 being formed, crystals is another proposition. That requires arduous
4 steps to arrive at.

5 JUDGE COLAIANNI: Is it your position that the prior art
6 does not teach a wetting agent in combination with lactic acid?

7 MR. TALAPATRA: The prior art does not teach a wetting
8 agent. The prior art teaches compositions -- teaches ingredients that
9 may also be wetting agents but not -- does not teach their use as a
10 wetting agent.

11 JUDGE NAGUMO: Isn't that really, though, what Percel is
12 talking about when he uses calcium lactate? I mean he says -- let's
13 see. This is towards the bottom of column 2. "The reason for this is
14 that the calcium lactate was found to be a particularly suitable carrier.
15 Not only is it capable of absorbing more lactic acid but, in addition,
16 depleted calcium lactate can be effectively coated with a lipid," and
17 that's precisely why Applicants use things like calcium lactate because
18 it can be effectively coated with a lipid, and so it is performing as a
19 wetting agent both in Applicant's condition and, also, it seems like that
20 in Percel.

21 You use a substrate that is readily coated by the encapsulant
22 because if you have any bare spots, that helps, especially with
23 something that's hard to coat, like lactic acid.

24 MR. TALAPATRA: I understand your concern, your Honor.
25 The use is distinguishable, however, even though the same material
26 can be used both as a carrier and as a wetting agent, and that is

1 probably best evidenced by the fact that when calcium lactate is used
2 as a carrier, a far greater amount needs to be used than when used as a
3 wetting agent.

4 So in the present invention, for example, the Appellants are
5 able to get well over 90 percent, even 95 to 99 percent, calcium lactic
6 acid in crystalline form into a composition using only from 5 percent
7 to .5 percent of a wetting agent.

8 JUDGE NAGUMO: How would you argue that that affects the
9 patentability of claim 1? Is that an argument for unexpected results or
10 is it an argument against the prima facie case of obviousness?

11 MR. TALAPATRA: Appellants appreciate that in order to
12 make that distinction, perhaps an amendment might be required to the
13 claims, but that doesn't get away from the fact that Percel does not
14 teach the use of calcium lactic acid -- crystalline lactic acid -- pardon
15 me -- and for the reasons we mentioned, that the evidence of record
16 would also suggest that the lactic acid in Percel is not crystalline.

17 JUDGE NAGUMO: Thank you. I think I understand your
18 position.

19 MR. VILLACORTA: May I add something, your Honor, if I
20 may?

21 JUDGE NAGUMO: Go ahead.

22 MR. VILLACORTA: I think that the reference to Percel can
23 be used as both an argument against the prima facie case of
24 obviousness and also for non-expected results, because, on the one
25 hand, Percel teaches the use of calcium lactate only in terms of a
26 substrate and not as a wetting agent, as is used by the Applicants, and,

1 therefore, I don't believe that the Examiner's rejection has risen to a
2 level of a prima facie case because it is missing that critical element of
3 a wetting agent.

4 Secondly, I believe that the Percel reference teaches away from
5 what the Inventors have done here because, again, they are using it in
6 a large amount as a substrate over which is coated the lactic acid and,
7 therefore, one would not have been reasonably disposed to expecting
8 that you can use just a little bit of the wetting -- lactic acid -- a little bit
9 of the calcium lactate, rather, as a wetting agent, as opposed to using it
10 in large amounts as a carrier. Thank you.

11 JUDGE SMITH: No more questions?

12 JUDGE NAGUMO: No.

13 JUDGE SMITH: Thank you. Your case has been submitted

14 Whereupon, the proceedings at 2:07 p.m. were concluded.